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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,672	01/21/2004	David S. Garvey	102258.137US1	1938

25270 7590 01/13/2005

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/760,672	Applicant(s) GARVEY ET AL.	
	Examiner Maury Audet	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142 applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1-38. Claims 1-4, drawn to one of the following 37 methods, namely methods for treating, preventing and/or reducing inflammation (1), pain (2), and fever (3); for decreasing or reversing the gastrointestinal (4), renal (5) and other toxicities (6, list which one) resulting from the use of nonsteroidal anti-inflammatory compounds; for treating and/or preventing gastrointestinal disorders (7); for treating inflammatory disease states and disorders (9); for treating and/or preventing ophthalmic diseases or disorders (10); for treating and/or improving the gastrointestinal properties of COX-2 inhibitors (11); for treating and/or preventing renal toxicity (12); for treating and/or preventing COX-2 mediated disorders (13, list which one); for decreasing the recurrence of ulcers (14); for improving gastroprotective properties, anti-Helicobacter pylori properties or antacid properties of proton pump inhibitors (15); for treating and/or preventing bacterial infections (16, list which one); microbial infections (17, list which one); multiple sclerosis (18); and/or viral infections (19); for improving gastroprotective properties of H2 receptor antagonists (20); for treating or preventing restenosis (21), autoimmune diseases (22), pathological conditions resulting from abnormal cell proliferation (23), polycystic kidney disease (24), inflammatory diseases (25, list which one) or to inhibit wound contraction

(26); for treating or preventing sexual dysfunctions in males and females (27), for enhancing sexual responses in males and females (28); for treating or preventing benign prostatic hyperplasia (29), hypertension (30), neurodegenerative disorders (31, list which one), vasospastic diseases (32, list which one), cognitive disorders (33, list which one), urge incontinence (34), or an overactive bladder (35); for reversing the state of anesthesia (36); for treating or preventing diseases induced by the increased metabolism of cyclic guanosine 3',5'-monophosphate (cGMP) (37); for treating respiratory disorders (38, list which one),

comprising administering at least one compound of **Formula I** or pharmaceutically acceptable salts thereof, classified in class 514, subclass 18+.

39-75. Claims 1-3, and 5, drawn to one of the following 37 methods, namely methods for treating, preventing and/or reducing inflammation (39), pain (40), and fever (41); for decreasing or reversing the gastrointestinal (42), renal (43) and other toxicities (44, list which one) resulting from the use of nonsteroidal anti-inflammatory compounds; for treating and/or preventing gastrointestinal disorders (45); for treating inflammatory disease states and disorders (46); for treating and/or preventing ophthalmic diseases or disorders (47); for treating and/or improving the gastrointestinal properties of COX-2 inhibitors (48); for treating and/or preventing renal toxicity (49); for treating and/or preventing COX-2 mediated disorders (50, list which one); for decreasing the recurrence of ulcers (51); for improving gastroprotective properties, anti-Helicobacter pylori properties or antacid properties of proton pump inhibitors (52); for treating and/or preventing bacterial infections (53, list which one); microbial infections (54, list which one); multiple sclerosis (55); and/or viral infections (56); for improving gastroprotective properties of H2 receptor antagonists (57); for treating or preventing restenosis (58), autoimmune

diseases (59), pathological conditions resulting from abnormal cell proliferation (60), polycystic kidney disease (61), inflammatory diseases (62, list which one) or to inhibit wound contraction (63); for treating or preventing sexual dysfunctions in males and females (64), for enhancing sexual responses in males and females (65); for treating or preventing benign prostatic hyperplasia (66), hypertension (67), neurodegenerative disorders (68, list which one), vasospastic diseases (69, list which one), cognitive disorders (70, list which one), urge incontinence (71), or an overactive bladder (72); for reversing the state of anesthesia (73); for treating or preventing diseases induced by the increased metabolism of cyclic guanosine 3',5'-monophosphate (cGMP) (74); for treating respiratory disorders (75, list which one),

comprising administering at least one compound of **Formula II** or pharmaceutically acceptable salts thereof, classified in class 514, subclass 18+.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-38 and 39-75 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods of using a peptide of either Formula I or Formula II. Since Formula II does not contain a disulphide bond, as Formula I does, the two compounds necessarily convey different effects when used in the various 38 distinct methods of using the either Formula, absent evidence to contrary. Furthermore, a search of Formula I would not be coextensive with a search of Formula II, based on the different structures of the two formulas and their respective compound species.

Inventions 1-38 and 39-75 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used to a treat any one of the 37 diseases above (i.e. CHF, glaucoma, etc.).

The methods of Groups 1-38 and 39-75 are directed to different inventions, which are not connected in design, operation, and/or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Because these inventions are distinct for the reasons given above and the search required for each group is not necessarily required for the other groups, restriction for examination purposes as indicated is proper.

Election of a Single Method of Using Single Peptide

In addition to electing a method of use, using either Formula I (any one of Group 1-38) or Formula II (any one of Groups 39-75), Applicant is required to elect a **single method of use** to which either Formula I or Formula II will be examined on the merits (i.e. Formula I for treating glaucoma), because no meaningful search can be conducted without a undue burden, due to the myriad of potential methods of using either Formula I or Formula II. Thus, a separate and distinct search, as well as examination of each Formula and method of use is required. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each method is assumed to be patentably distinct invention, in the absence of evidence to the contrary.**

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 01/09/2005

CHRISTOPHER R. TATE
PRIMARY EXAMINER